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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,997	06/08/2001	Jean-Baptiste Dumas Milne Edwards	78.US4.CIP	2239

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EXAMINER	
RAMIREZ, DELIA M	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/876,997	DUMAS MILNE EDWARDS ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-25,27,28,30 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-25,27,28,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *6/21/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/21/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 23-25, 27-28,30-31 are pending.

Applicant's amendment of claims 23-24, cancellation of claims 26, 29, 32-34, submission of references, and submission of an alignment, in a communication filed on 6/21/2004 are acknowledged.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 6/21/2004 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

2. The formal drawings submitted on 6/21/2004 are accepted by the Examiner.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 23-25, 27-28,30-31 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial and specific asserted utility or a well established utility. This rejection has been discussed at length in the Office Action mailed on 8/21/2003.

5. Applicants argue that the identification of the claimed polypeptide as a member of the PAP2 family is not based on sequence alignment alone. Applicants submit that the alignment presented as Appendix 1 shows a high e-value and that the polypeptide of SEQ ID NO: 399 displays a conserved phosphatase signature motif. Applicants refer to the teachings of Stacey et al. and assert that the presence of this motif serve as a predictor of phosphatase function. Therefore, it is applicant's contention that one of skill in the art would reasonably conclude that the polypeptide of SEQ ID NO: 399 is a phosphatidic acid phosphatase. Applicants submit that the references cited by the Examiner fail to establish that the function assigned to the polypeptide of SEQ ID NO: 399 is not credible. According to Applicants, (1) Attwood et al. teaches that motifs usually reflect some vital structural and functional role, (2) the teachings of Van de Loo et al., Seffernick et al., and Broun et al. illustrate exceptions and do not address the issue of function determination based on signature motifs and/or Pfam domains, and (3) the teachings of Witkowski et al. refer to mutagenesis at the catalytic site whereas the signature motif and residues involved in catalytic activity in the polypeptide of SEQ ID NO: 399 are conserved. In addition, it is applicant's contention that phosphatidic acid phosphatases have a substantial and well-established utility and that one of skill in the art would know how to use them. Applicants submit the references by Brindley et al. and Abraham et al. in support of the argument that phosphatidic acid phosphatases play a role in decreasing cell division, obesity, insulin resistance, and cirrhosis. Therefore, the polypeptide of SEQ ID NO: 399 can be used to identify agents which modulate its activity and would have a real-world utility.

6. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the instant rejection. For the record, It is noted that no reference by Stacey et al. was found in the submission filed on 6/21/2004. It appears that the intended reference is that of Stukey et al. (Protein Science 6:469-472, 1997). The Examiner acknowledges the alignment submitted as well as the teachings of Stukey et al. However, the Examiner disagrees with

applicant's contention that the presence of the phosphatase motif and a PAP2 Pfam domain is sufficient for one of skill in the art to reasonably conclude that the claimed polypeptide has a specific and substantial or well-established utility. While credibility is not being assessed herein, it is noted that the teachings of Stukey et al. in regard to the phosphatase motif indicate that this motif is shared by several lipid phosphatases and not only by PAP2 family members. Furthermore, none of the alleged domains/motifs provide any information as to the specific substrate for the alleged phosphatase or the specific biological processes associated with the polypeptide of SEQ ID NO: 399. Thus, while one could argue that the polypeptide of SEQ ID NO: 399 is a phophatase, neither the specification nor the art provide any information as to the specific biological activity associated with the polypeptide of SEQ ID NO: 399. In regard to the references provided previously by the Examiner, while it is agreed that (1) members of a protein family must share some structural elements which allow them to be classified in a general protein family, (2) the teachings of Van de Loo et al., Seffernick et al., and Broun et al. are examples of how small structural changes result in changes in proteins, and (3) the conservative amino acid substitution in the enzyme of Witkowski et al. occurred in the catalytic domain, it is noted that these references were introduced as evidence to show the unpredictability of assigning function based on structural homology and how even small changes can result in changes in function. Also, it is noted that in some of these examples, it was assumed that the highly structurally homologous proteins tested had the same function as they shared structural features which were known to be associated to that function (i.e. domains).

In regard to arguments that phosphatidic acid phosphatases have substantial and well-established utility since these phosphatases are associated with decreasing cell division, obesity, insulin resistance and cirrhosis, it is noted that even if one were to assume that the polypeptide of SEQ ID NO: 399 is indeed a phosphatidic acid phosphatase, as indicated previously, there is no clue as to the specific substrate or biological function associated with the polypeptide of SEQ ID

NO: 399. Applicants assert that phosphatidic acid phosphatases are associated with several different biological processes (i.e. decreasing cell division, obesity, insulin resistance and cirrhosis), and therefore the alleged phosphatidic acid phosphatase of SEQ ID NO: 399 can be used to test modulators of its activity for therapeutic use. However nowhere in the specification or the art can one find the specific biological process in which the polypeptide of SEQ ID NO: 399 plays a role and it is not expected that all phosphatidic acid phosphatase are involved in decreasing cell division, obesity, insulin resistance and cirrhosis. Therefore, even if one assumes that the polypeptide of SEQ ID NO: 399 is a phosphatidic acid phosphatase, the claimed polypeptide lacks a specific and substantial or well-established utility as its specific substrate and/or biological role are unknown. In addition, even if one could determine modulators of its activity, the claimed polypeptide lacks a specific and substantial or well-established utility as a target for testing activity modulators in view of the fact that the specific diseases/disorders which can be treated with its modulators are unknown. It would require further research to identify the specific substrates, biological function, and diseases/disorders associated with the polypeptide of SEQ ID NO: 399. Thus, one cannot reasonably conclude that the claimed polypeptide meets the utility requirements set forth in 35 USC 101.

7. Claims 23-25, 27-28,30-31 also remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112, First Paragraph

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 25, 28, 31 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. This rejection was made in regard to a biological deposit requirement.

10. In view of applicant's statement in page 5, lines 9-11 of the Remarks section submitted on 6/21/2004, indicating that the recited clone has been deposited under the terms of the Budapest Treaty and that the clone will be irrevocably, and without restriction or condition, released to the public upon issuance of a patent, this rejection is hereby withdrawn.

Double Patenting

11. It is noted that application Serial No. 09/731,872 is now abandoned. With respect to Applicant's comment regarding application Serial No. 10/643836, which is a divisional of application Serial No. 09/731,872, upon visual inspection of the sequence listings, it appears that the claimed polypeptide in said application (SEQ ID NO: 297, 132 amino acids) and the polypeptide of the instant application (SEQ ID NO:399; 180 amino acids) are not the same.

Conclusion

12. No claim is in condition for allowance.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 872-9306. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
October 12, 2004

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1800~~ 1600